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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC.,)	
)	
)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 24-_____
)	
ACCORD HEALTHCARE INC.,)	
INTAS PHARMACEUTICALS,)	
LIMITED,)	
)	
Defendants.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement by Esperion Therapeutics, Inc. (“Esperion”) under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Accord Healthcare Inc. and Intas Pharmaceuticals Limited (collectively “Accord”). This action arises out of Accord’s submission of Abbreviated New Drug Application (“ANDA”) No. 219430 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of NEXLETOL[®] prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, and 11,926,584 (collectively, the “Asserted Patents”).

PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

3. Upon information and belief, Defendant Accord Healthcare Inc. (“Accord Healthcare”) is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

4. Upon information and belief, Accord Healthcare is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

5. Upon information and belief, Accord Healthcare directly or through its affiliates, markets and sells drug products throughout the United States, including in the state of New Jersey.

6. Upon information and belief, Defendant Intas Pharmaceutical Limited (“Intas”) is a corporation organized and existing under the laws of India, having a place of business at Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad, 380054, Gujarat, India.

7. Upon information and belief, Intas is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

8. Upon information and belief, Intas directly or through its affiliates, including Accord Healthcare, markets and sells drug products throughout the United States, including in the state of New Jersey.

9. Upon information and belief, Accord Healthcare is a wholly owned subsidiary of Intas.

10. Upon information and belief, Intas directs or controls the operations, management, and activities of Accord Healthcare in the United States.

11. Upon information and belief, Intas and Accord Healthcare are agents of each other and/or operate in concert as integrated parts of the same business group.

12. Upon information and belief, Accord Healthcare and Intas act in concert to directly or through its affiliates market and sell drug products throughout the United States, including in New Jersey.

13. Upon information and belief, Accord Healthcare and Intas work in concert on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

14. Upon information and belief, Accord Healthcare and Intas acting in concert prepared and submitted ANDA No. 219430 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL[®] (the “Accord ANDA Product”) prior to the expiration of the Asserted Patents.

15. Upon information and belief, Accord Healthcare and Intas acting in concert developed the Accord ANDA Product.

16. Upon information and belief, Accord Healthcare and Intas acting in concert are seeking regulatory approval from the FDA to market and sell the Accord ANDA Product throughout the United States, including in New Jersey.

17. Upon information and belief, Accord Healthcare and Intas intend to obtain approval for Accord’s ANDA No. 219430, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Accord ANDA Product in the United States, including in New Jersey.

JURISDICTION AND VENUE

18. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

19. This Court has personal jurisdiction over Accord Healthcare for this action because Accord Healthcare, through its counsel, consented to personal jurisdiction in the District of New Jersey for purposes of this action prior to the filing of this Complaint.

20. This Court also has personal jurisdiction over Accord Healthcare and Intas because both have litigated previous Hatch-Waxman patent litigation disputes in the District of New Jersey and consented to or did not contest personal jurisdiction in this Court for purposes of those actions including in at least *Fresenius Kabi USA, LLC v. Accord Healthcare Inc.*, C.A. No. 22-cv-06341, Dkt. 1 (D.N.J. filed Oct. 28, 2022); *Janssen Pharmaceuticals, Inc. et al. v. Accord Healthcare Inc.*, C.A. No. 22-cv-00856, Dkt. 1 (D.N.J. filed Feb. 16, 2022); *Eagle Pharmaceuticals, Inc. v. Accord Healthcare Inc.*, C.A. No. 19-cv-09031, Dkt. 11 (D.N.J. filed Apr. 15, 2019). Accord Healthcare and Intas have also affirmatively availed themselves of the jurisdiction of this Court by filing counterclaims in this Court including in at least *Otsuka Pharma. Co., Ltd. v. Intas Pharma. Ltd.*, C.A. No. 16-cv-5743, Dkt. 11 (D.N.J. filed Feb. 13, 2017); *Sanofi-Aventis US LLC v. Accord Healthcare, Inc.*, Civ. No. 14-cv-8079, Dkt. 9 (D.N.J. filed Feb. 10, 2015); *Otsuka Pharma. Co. v. Intas Pharm. Ltd., Accord Healthcare, Inc.*, C.A. No. 14-cv-3996, Dkt. 45 (D.N.J. filed Dec. 8, 2014).

21. This Court also has personal jurisdiction over Accord Healthcare and Intas because, among other things, they have both, acting in concert, committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of ANDA No. 219430 in New Jersey, and intend to engage in a future course of

conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219430, Accord Healthcare and Intas, acting in concert, will make, use, import, sell, and/or offer for sale the Accord ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

22. Finally, this Court also has personal jurisdiction over Accord Healthcare and Intas because, among other things, this action arises from Accord Healthcare and Intas' actions directed toward New Jersey, and because, upon information and belief, Accord Healthcare and Intas have purposefully availed themselves of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; (3) creating a presence in New Jersey through its registration with the New Jersey Department of Health as a drug manufacturer and wholesaler and maintains a Drug and Medical Device Certificate of Registration under Registration No. 5003815; and (4) working in concert to develop and market pharmaceutical products, including in New Jersey, with their subsidiary Essential Pharmaceuticals LLC a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 8041 Arco Corporate Drive, Suite 200 Raleigh, NC 27617 and registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0600277360. <https://www.essentialpharma.com/about/> (last visited May 14, 2024). Accord Healthcare and Intas therefore have purposely availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being hailed into court here.

23. Upon information and belief, Intas' contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Intas denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court has personal jurisdiction over Intas pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Intas is not subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole.

24. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Accord Healthcare and Intas to litigate this action in this Court, and Accord Healthcare and Intas are subject to personal jurisdiction in New Jersey.

25. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

26. Venue is proper in this Court because, among other things, Accord Healthcare, through its counsel, consented to venue in the District of New Jersey for purposes of this action prior to the filing of this Complaint.

27. Venue is also proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b) because Accord Healthcare and Intas have a regular and established place of business in New Jersey at least because, upon information and belief, they: (1) have sought approval from the FDA to market and sell Accord Healthcare and Intas' proposed generic NEXLETOL[®] product in New Jersey; and (2) have engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

28. Venue is proper in this Court as to Intas under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, Intas is a corporation organized under the laws of

India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

THE PATENTS-IN-SUIT

29. U.S. Patent No. 11,760,714 (the “’714 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on September 19, 2023. A true and correct copy of the ’714 Patent is attached hereto as “Exhibit A.”

30. Esperion is the assignee of, and holds all rights, title and interest in the ’714 Patent.

31. The ’714 Patent currently expires on June 19, 2040.

32. U.S. Patent No. 11,613,511 (the “’511 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on March 28, 2023. A true and correct copy of the ’511 Patent is attached hereto as “Exhibit B.”

33. Esperion is the assignee of, and holds all rights, title and interest in the ’511 Patent.

34. The ’511 Patent currently expires on June 19, 2040.

35. U.S. Patent No. 11,926,584 (the “’584 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on March 12, 2024. A true and correct copy of the ’584 Patent is attached hereto as “Exhibit C.”

36. Esperion is the assignee of, and holds all rights, title and interest in the ’584 Patent.

37. The ’584 Patent currently expires on June 19, 2040.

38. All claims of the ’714, ’511, and ’584 Patents are valid, enforceable, and not expired.

ESPERION’S NEXLETOL PRODUCT

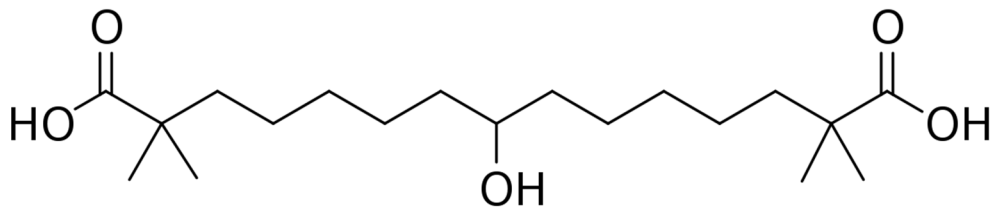
39. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL®.

40. Esperion is the holder of New Drug Application (“NDA”) No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the

United States under the trade name “NEXLETOL®.” Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

41. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

42. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



43. The claims of the Asserted Patents cover NEXLETOL®.

44. The Asserted Patents have been listed in connection with NEXLETOL® in the FDA’s publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the “Orange Book.”

ACCORD’S ANDA PRODUCT

45. By letter dated April 2, 2024, and received by Esperion via Federal Express on April 3, 2024 (the “April 2nd Notice Letter”), Accord notified Esperion that Accord had submitted ANDA No. 219430 to the FDA for a generic version of NEXLETOL®.

46. In the April 2nd Notice Letter, Accord stated that ANDA No. 219430 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’714 and ’511 Patents. Accord also contended that the ’714 and ’511 are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Accord ANDA Product.

47. By letter dated April 23, 2024, and received by Esperion via Federal Express on April 23, 2024 (the “April 23rd Notice Letter”), Accord notified Esperion that Accord had submitted an amended patent certification to ANDA No. 219430.

48. In the April 23rd Notice Letter, Accord stated that it had submitted an amended certification to ANDA No. 219430 to also include a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’584 Patent. Accord also contended that the ’584 is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Accord ANDA Product.

49. The April 2nd and April 23rd Notice Letters state that Accord seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Accord ANDA product before the expiration of the Asserted Patents. Upon information and belief, Accord intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Accord ANDA product promptly upon receiving FDA approval to do so.

50. By submitting ANDA No. 219430, Accord has represented to the FDA that the Accord ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL[®] and is bioequivalent to NEXLETOL[®].

51. Upon information and belief, Accord has knowledge of the Asserted Patents and had knowledge of at least the '714 and '511 patents when it initially submitted ANDA No. 219430 to the FDA.

52. Upon information and belief, Accord Healthcare intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product immediately and imminently upon approval of ANDA No. 219430.

53. Upon information and belief, Intas will manufacture the Accord ANDA Product and import the Accord ANDA Product to the United States for use, sale and offer for sale immediately and imminently upon approval of ANDA No. 219430.

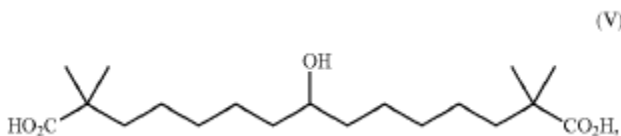
54. On or about May 3, 2024, pursuant to an Offer of Confidential Access, Accord produced portions of its ANDA No. 219430 to Esperion.

55. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the April 2nd and April 23rd Notice Letters.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714

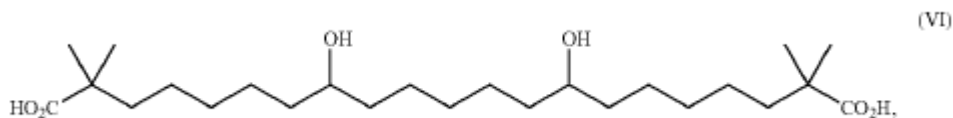
56. Esperion incorporates each of the preceding paragraphs 1 – 55 as if fully set forth herein.

57. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the

compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

58. Accord's submission of ANDA No. 219430 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

59. Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product prior to expiration of the '714 Patent, and Accord's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

60. Upon information and belief, upon FDA approval of ANDA No. 219430, Accord intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Accord ANDA Product, unless enjoined by the Court.

61. Upon information and belief, by virtue of their listing in the Orange Book and identification in Accord's April 2nd and April 23rd Notice Letters, Accord has knowledge of the Asserted Patents and knowledge that its Accord ANDA Product will infringe the Asserted Patents.

62. Upon information and belief, Accord intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No.

219430 is approved by marketing the Accord ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

63. Upon information and belief, Accord intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219430 is approved, unless enjoined by the Court, because Accord knows that the Accord ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Accord ANDA Product is not suitable for substantial noninfringing use.

64. Accord's infringement is imminent because, among other things, Accord has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product before the expiration of the '714 Patent.

65. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

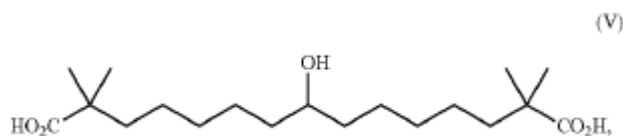
66. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Accord's making, using, offering to sell, selling, and/or importing the Accord ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

67. Unless Accord is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

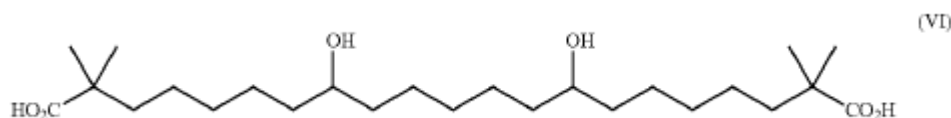
COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,613,511

68. Esperion incorporates each of the preceding paragraphs 1 – 67 as if fully set forth herein.

69. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

70. Accord's submission of ANDA No. 219430 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

71. Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product prior to expiration of the '511 Patent, and Accord's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

72. Upon information and belief, upon FDA approval of ANDA No. 219430, Accord intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either

literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Accord ANDA Product, unless enjoined by the Court.

73. Upon information and belief, by virtue of their listing in the Orange Book and identification in Accord's April 2nd and April 23rd Notice Letters, Accord has knowledge of the Asserted Patents and knowledge that its Accord ANDA Product will infringe the Asserted Patents.

74. Upon information and belief, Accord intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219430 is approved by marketing the Accord ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

75. Upon information and belief, Accord intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219430 is approved, unless enjoined by the Court, because Accord knows that the Accord ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Accord ANDA Product is not suitable for substantial noninfringing use.

76. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

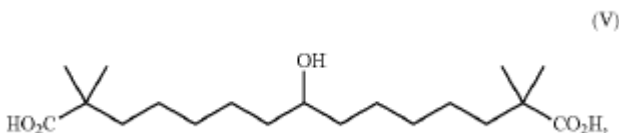
77. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Accord's making, using, offering to sell, selling, and/or importing the Accord ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

78. Unless Accord is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

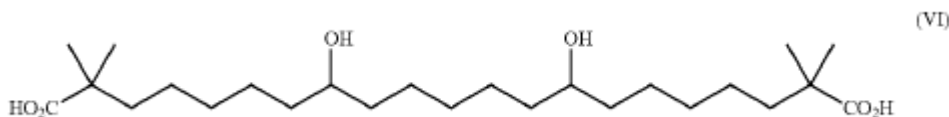
COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,926,584

79. Esperion incorporates each of the preceding paragraphs 1 – 78 as if fully set forth herein.

80. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



81. Accord's submission of ANDA No. 219430 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product before the expiration of the '584 Patent constituted an act of direct and/or indirect infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

82. Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product prior to expiration of the '584 Patent, and Accord's inducement of

and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

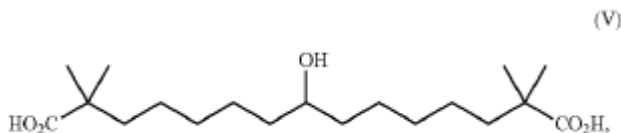
83. Upon information and belief, upon FDA approval of Accord's ANDA No. 219430, Accord will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Accord ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

84. Upon information and belief, Accord specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219430 is approved by marketing the Accord ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

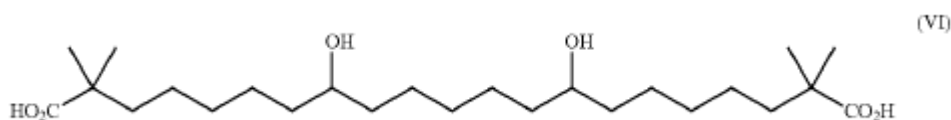
85. Upon information and belief, Accord's ANDA No. 219430 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Accord ANDA Product.

86. Upon information and belief, upon FDA approval of ANDA No. 219430, Accord intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Accord ANDA Product, unless enjoined by the Court, and the Accord ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

87. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



88. Upon information and belief, the use of the Accord ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

89. Upon information and belief, by virtue of their listing in the Orange Book and identification in Accord's April 2nd and 23rd Notice Letters, Accord has knowledge of the Asserted Patents.

90. On information and belief, Accord is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Accord ANDA Product at least according to Accord's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

91. Upon information and belief, Accord intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219430 is approved, unless enjoined by the Court, because Accord knows that the Accord ANDA Product is

especially made or adapted for use in infringing the '584 Patent, and that the Accord ANDA Product is not suitable for substantial noninfringing use.

92. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

93. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Accord's making, using, offering to sell, selling, and/or importing the Accord ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

94. Unless Accord is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Esperion asks that this Court grant the following relief:

95. A judgment that the claims of the Asserted Patents are infringed by Accord's submission of ANDA No. 219430 under 35 U.S.C. § 271(e)(2)(A);

96. A declaratory judgment that Accord's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Accord ANDA Product prior to the expiration of the Asserted Patents, would infringe the Asserted Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

97. A judgment that the Asserted Patents are not invalid or unenforceable;

98. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Accord's ANDA No. 219430 shall not be earlier than the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

99. An order permanently enjoining Accord, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Accord, from making, using, offering to sell, selling, or importing the Accord ANDA Product until after the Asserted Patents' expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

100. Damages or other monetary relief, including costs, fees, pre-judgment interest and post-judgment interest to Esperion if Accord engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Accord ANDA Product prior to the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

101. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285; and

102. Such further and other relief as this Court deems proper and just.

Dated: May 16, 2024

/s/ Liza M. Walsh

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following actions:

- *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc., et al.*, Civil Action No. 2:24-cv-05921-JXN-CLW
- *Esperion Therapeutics, Inc. v. Renata Limited., et al.*, Civil Action No. 2:24-cv-06017-JXN-CLW

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: May 16, 2024

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